S.N. 10/811,130 Amendment and Response Attorney Docket CHM-015

## Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

## **Listing of Claims:**

- 1. (canceled)
- 2. (currently amended) The method according to Claim <u>66</u>[[30]] wherein the urine sample comprises a plurality of urine samples from the <u>mammal subject</u> that are obtained intermittently or continuously.
- 3. (canceled)
- 4. (currently amended) The method according to Claim <u>66</u>[[31]] wherein the step of detecting the antibody-NGAL complex comprises contacting the complex with a second antibody for detecting the NGAL.
- 5. (currently amended) The method according to Claim <u>66</u>[[30]] wherein the <u>mammal</u> mammalian subject is a human.
- 6. 8. (canceled)
- 9. (currently amended) The method according to Claim <u>66</u>[[31]] wherein the antibody is a capture antibody for the NGAL and the antibody-NGAL complex is a capture antibody-NGAL complex.

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10. (previously presented) The method according to Claim 9 wherein the step of detecting the

antibody-NGAL complex comprises the steps of:

(1) separating any unbound material of the urine sample from the capture antibody-

NGAL complex;

(2) contacting the capture antibody-NGAL complex with a second antibody for detecting

the NGAL, to allow formation of a second complex between the second antibody and the capture

antibody-NGAL complex;

(3) separating any unbound second antibody from the second antibody complex; and

(4) detecting the second antibody of the second antibody complex.

11. (previously presented) The method according to Claim 10 wherein the step (i) comprises the

step of contacting the urine sample with a media having affixed thereto the capture antibody.

12. - 32. (canceled)

33. (currently amended) The method according to claim 66[[30]], wherein the obtained urine

sample is the first urine output of the mammal subject immediately after the onset of the RTCI

following the event.

34. (canceled)

35. (currently amended) The method according to claim 66[[30]] wherein the urine sample is

obtained within a period of time of the RTCI, the period of time [[is]] selected from the group

consisting of 6 hours, 4 hours, 3 hours, 1 hour, and 30 minutes.

36. (canceled)

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37. (currently amended) The method according to claim <u>66</u>[[30]] wherein the <u>RTCI is effected</u> <u>by an event upon the mammal, the event [[is]]</u> selected from the group consisting of: (a) a surgical procedure selected from the group consisting of open heart surgery, cardiac surgery, and vascular surgery; and (b) kidney transplantation.

38. - 54. (canceled)

55. (currently amended) The method according to claim <u>66</u>[[31]] wherein the level of <u>detected</u> <u>antibody-NGAL complex</u> correlates with the extent of the acute ischemic renal tubular cell injury.

56. - 59. (canceled)

60. (currently amended) The method according to claim <u>66</u>[[1]] wherein the mammal is a patient who has undergone open heart surgery, and wherein an the elevated level of antibody NGAL complex is at least [[a]] 10-fold increase in the level of antibody-NGAL complex in a urine sample obtained at 2 hours, correlates with the RTCI progressing to acute renal failure (ARF).

61. - 65. (canceled)

- 66. (new) A method for the detection of a renal tubular cell injury (RTCI) in a mammal, the RTCI being an ischemic renal injury, comprising the steps of:
- (a) contacting a urine sample obtained within four hours of the RTCI from a mammal suspected of having the RTCI, with an antibody for a biomarker consisting of NGAL, to allow formation of a complex of the antibody and NGAL;
  - (b) detecting the antibody-NGAL complex; and
- (c) correlating the level of detected antibody-NGAL complex to the mammal having the RTCI.